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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1753	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/663,153	Applicant(s) FELDMAN ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1753	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *preliminary amendment of 08/08/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/08/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS of* .

DETAILED ACTION

Claim Objections

1. Claims 1 and 16 are objected to because of the following informality: in line 11 of claim 1 and in line 11 of claim 16 there appears to be a period at the end of the line instead of a semicolon. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 8-11, 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO English language machine translation of Ryohei et al. (JP 09-159642 A) ("Ryohei I") in view of Hodges et al. (US 5,942,102) ("Hodges I") and Hodges et al. (WO 97/00441) ("Hodges II").

Addressing claims 1, 9, and 10 Ryohei I discloses a sensor strip for determining the concentration of an analyte in a sample (the abstract) comprising:

(a) a first substrate (1a) having a proximal end and an opposite distal end (Drawing 1), the distal end being configured and arranged for insertion into a sensor reader (note connection terminal 23 and see [0012] in Detailed Description), the first substrate defining a first edge (left side edge in Drawing 1) and a second edge (right

side edge in Drawing 1) of the sensor extending from a proximal end to the distal end of the first substrate (Drawing 1);

(b) a second substrate (1b) positioned over the first substrate (Drawings 1 and 3);

(c) at least one working electrode (221) on the first substrate (Drawings 1 and 3); and

(d) at least one counter electrode (222) on the second substrate (Drawings 1 and 3), with a portion of the counter electrode located 25-1000 micrometers from a portion of the at least one working electrode (the working electrode and the counter electrode are separated by a spacer (4) that is 50-300 micrometers thick ([0017] in Detailed Description);

(e) a spacer (4) between the first and second substrates (Drawings 1 and 3) defining:

(i) a first aperture (61) along the proximal end of the sensor (Drawing 2), and

(ii) a sample chamber extending from the first aperture to a second aperture (62) (Drawing 2), the sample chamber comprising a measurement zone having a small volume (Technical Field and Effect of Invention), and the sample chamber defining a recess having at least a portion of the working electrode and redox mediator situated in the recess (Drawing 1 – note the reaction layer (3) and see [0022] in Detailed Description, which discloses ferrocene carboxylic acid mixed with glucose oxidase).

Ryohei I does not mention the volume of the measurement zone, although as noted above the sensor strip is intended for use with a small sample.

Hodges I discloses a sensor strip for determining the concentration of an analyte in a sample (the abstract) comprising:

(a) a first substrate (7) having a proximal end and an opposite distal end (Figure 9), the distal end, the first substrate defining a first edge (left side edge in Figure 9) and a second edge (right side edge in Figure 9) of the sensor extending from a proximal end to the distal end of the first substrate (Figure 9);

(b) a second substrate (1) positioned over the first substrate (Figure 9);

(c) at least one working electrode (6) on the first substrate (Figure 9); and

(d) at least one counter electrode (3) on the second substrate (Figure 9), with a portion of the counter electrode located 25-1000 micrometers from a portion of the at least one working electrode (the working electrode and the counter electrode are separated by a spacer (4) that is 100 microns thick (col. 04:56-57);

(e) a spacer (4) between the first and second substrates (Figure 9) defining:

(i) a first aperture (left notch in Figure 9), and

(ii) a sample chamber (8) with a second aperture (right notch in Figure 9), the sample chamber comprising a measurement zone having a volume of no more than 1 microlitre (The sample chamber is 100 microns thick and has a 3.4 mm diameter. Some simple calculations reveal that the sample chamber has a cross-sectional area = 9.1 mm^2 and volume = 0.91 mm^3 = 0.91 microlitre), and

the sample chamber defining a recess having at least a portion of the working electrode and redox mediator situated in the recess (col. 05:08-10).

Hodges II discloses a sensor strip comprising a cell made from opposing substrates with a working electrode on one substrate and a counter electrode on the other substrate; the electrodes being spaced apart by less than 500 microns, preferably 20-400 microns, and more preferably 20-200 microns; the effective cell volume, which includes the measurement zone, being 1.5 microlitres or less; and the cell containing redox mediator. See page 15, lines 17-23 and page 16, lines 08-12. An effective cell volume of 1.5 microlitres presumably corresponds to a spacing between the electrodes of 500 microns or at least 200 microns. So, a spacing between the electrodes of 20 microns, the lowest stated limit, should bring the effective cell volume significantly below 1 microlitre.

Thus, barring evidence to the contrary, such as unexpected results, in light of Hodges I and Hodges II having the measurement zone volume in the sensor strip of Ryohei I be no more than 1 microliter, or 0.5 microliter, or 0.2 microliter is just a matter of scaling down the dimensions of the sensor strip, in particular, this can be achieved by just using a thinner spacer (recall that Ryohei I discloses a spacing only 50 microns), so that the sensor strip is optimally configured for smaller sample volumes.

Moreover, as taught by Hodges I in the prior art "... sample size is greater than desirable. It would be generally preferable to be able to make measurements on samples of reduced volume since this in turn enables use of less invasive methods to obtain samples." See col. 02:35-40.

Addressing claim 2, the sample chamber in Ryohei I is substantially rectangular. However, barring some showing of criticality, the shape of the sample chamber is a design choice, especially since as shown by Figure 9 of Hodges I a circular sample chamber was known at the time of the invention.

Addressing claims 3 and 4, Ryohei I discloses at least carbon electrodes. See [0016] in Means.

Addressing claim 5, as stated in the rejection of claim 1 the working electrode and the counter electrode are separated by a spacer (4) that is 50-300 micrometers thick ([0017] in Detailed Description). So having the spacer thickness no more than 0.2 mm (200 micrometers) is just a matter of scaling down the sensor for a range of smaller sample volumes than would be used if the spacer were more than 200 microns.

Addressing claim 8, recall that Ryohei I discloses a spacer that is from 50-300 micrometers thick. Barring a contrary showing, such as unexpected result, the thickness of the spacer, which determines the spacing between the electrodes, will be determined by the largest expected sample volume.

Addressing claim 11, Ryohei I discloses ferrocene carboxylic acid mixed with glucose oxidase. See [0022] in Detailed Description.

Addressing claim 13, for the additional limitation of this claim see [0022] in Detailed Description, which discloses ferrocene carboxylic acid mixed with glucose oxidase

Addressing claim 15, for the additional limitation of this claim see [0017] in Detailed Description.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO English language machine translation of Ryohei et al. (JP 09-159642 A) ("Ryohei I") in view of Hodges et al. (US 5,942,102) ("Hodges I") and Hodges et al. (WO 97/00441) ("Hodges II") as applied to claims 1-5, 8-11, 13, 15 above, and further in view of Maley et al. (US 5,601,694) ("Maley").

Addressing claim 6, Ryohei I as modified by Hodges I and Hodges II does not mention the working area of the working electrode.

Maley discloses an electrochemical sensor strip in which the working electrode is formed by screen printing and its working area is determined by the size of an opening in a dielectric layer over a conductive strip, which is how the working electrode in Ryohei I is formed. See in Maley the abstract; Figure 9B; and col. 15 42-44; and col. 12:46-55. In Ryohei I see Drawing 1 and note insulating layer 5. The working area of the working electrode in Maley is 0.00038 inch^2 (= 0.00025 cm^2). See col. 23:40-55. Thus, in light of Maley, since the sensor strip of Riyohei I is intended for use with a small amount of sample, to have the working area of the working electrode less than about 0.01 cm^2 is just a matter of scaling the sensor strip down for a smaller sample volumes.

Addressing claim 14, Ryohei I as modified by Hodges I and Hodges II does not mention providing a second working electrode on the first substrate.

Maley discloses an electrochemical sensor strip comprising a second working electrode on the first substrate. See col. 03:51-55; col. 05:04-14; and col. 06:17-29. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a second working electrode on the first substrate as taught by Maley in the invention of Ryohei I as modified by Hodges I and Hodges II because as taught by Maley this ".. serves to adjust for electrochemically active neutral species which may diffuse through a semi-permeable cover membrane, which is preferably spun-cast over the electrodes" and "... provide[s] efficiency over extend sampling periods." See col. 03:51-59 and col. 06:26-39.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO English language machine translation of Ryohei et al. (JP 09-159642 A) ("Ryohei I") in view of Hodges et al. (US 5,942,102) ("Hodges I") and Hodges et al. (WO 97/00441) ("Hodges II") as applied to claims 1-5, 8-11, 13, 15 above, and further in view of Ikeda et al. (US 5,650,002) ("Ikeda") and Carter et al. (US 5,628,890) ("Carter").

Ryohei I as modified by Hodges I and Hodges II does not mention providing at least one indicator electrode on at least one of the first and second substrates and positioned relative to the sample chamber to determine when the sample chamber contains sample.

Ikeda discloses an electrochemical sensor strip which has at
least one indicator electrode (7) on at least one of the first and second substrates and positioned relative to the sample chamber to determine when the sample chamber contains sample. See the abstract and Figure 1. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide an indicator electrode as taught by Ikeda in the invention of Ryohei I as modified by Hodges I and Hodges II because as taught by Ikeda then '... it can definitely determined whether or not a sample liquid supplied through the sample supply port has covered the entire reaction area." See col. 05:58-67. As taught by Carter "... an insufficient amount of sample to the electrodes [of an electrochemical sensor] tends to produce an artificially low response ..." See col. 01:29-34.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO English language machine translation of Ryohei et al. (JP 09-159642 A) ("Ryohei I") in view of Hodges et al. (US 5,942,102) ("Hodges I") and Hodges et al. (WO 97/00441) ("Hodges II") as applied to claims 1-5, 8-11, 13, 15 above, and further in view of Diebold et al. (US 5,437,999) and Yamauchi et al. (US 5,723,345) ("Yamauchi").

Ryohei I only mentions ferrocene carboxylic acid as a particular possible mediator.

Diebold discloses a sensor strip for determining the concentration of an analyte in a sample (the abstract) comprising:

(a) a first substrate (4) having a proximal end and an opposite distal end (Figure 1), the distal end being configured and arranged for insertion into a sensor reader (Figure 6 and col. 13:09-13), the first substrate defining a first edge (foreground side edge in Figure 5) and a second edge (background side edge in Figure 5) of the sensor extending from a proximal end to the distal end of the first substrate (Figure 5);

(b) a second substrate (31) positioned over the first substrate (Figures 5 and 6);

(c) at least one working electrode (3) on the first substrate (Figures 1 and 5); and

(d) at least one counter electrode (32) on the second substrate (Figures 3 and 5), with a portion of the counter electrode located from a portion of the at least one working electrode (the working electrode and the counter electrode are separated by a spacer (43), a first insulating layer (5) over the working electrode, and a second insulating layer (34) over the counter electrode – Figures 1, 3, and 5);

(e) a spacer (43) between the first and second substrates (Figure 5) defining:

(i) a first aperture (50) along the proximal end of the sensor (Figure 5), and

(ii) a sample chamber (49) extending from the first aperture to a second aperture (51) (Drawing 2), the sample chamber comprising a measurement zone having a small volume of no more than 3 microliters (col. 12:35-39), and the sample chamber defining a recess having at least a portion of the working electrode and redox mediator situated in the recess (Figure 5 and col. 12:18-26).

Diebold discloses a variety of mediators including osmium reodx mediator. See col. 12:18-32.

Yamauchi discloses an electrochemical sensor strip and large variety of typical enzymes and mediators, including an osmium redox mediator, which may be used in electrochemical sensor strips. See the abstract; Figure 2; and Tables 2 and 3 in columns 19-21.

In light of Diebold and Yamauchi the selection of redox mediator from known redox mediators at the time of the invention was within the skill of one with ordinary skill in the art at the time of the invention and is just a mater of optimizing the reagent system for the analyte of interest.

9. Claims 1-5, 8-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus"), Kanezawa et al. (US 5,095,407) ("Kanezawa"), "Enthone – Imaging Technologies Update" June 2001/Number 3) ("Enthone"), Hodges et al. (US 5,942,102) ("Hodges I") and Hodges et al. (WO 97/00441).

Addressing claim 2, Diebold discloses a sensor strip for determining the concentration of an analyte in a sample (the abstract) comprising:

(a) a first substrate (4) having a proximal end and an opposite distal end (Figure 1), the distal end being configured and arranged for insertion into a sensor reader (Figure 6 and col. 13:09-13), the first substrate defining a first edge (foreground side edge in Figure 5) and a second edge (background side edge in Figure 5) of the sensor extending from a proximal end to the distal end of the first substrate (Figure 5);

(b) a second substrate (31) positioned over the first substrate (Figures 5 and 6);

(c) at least one working electrode (3) on the first substrate (Figures 1 and 5); and

(d) at least one counter electrode (32) on the second substrate (Figures 3 and 5), with a portion of the counter electrode located from a portion of the at least one working electrode (the working electrode and the counter electrode are separated by a spacer (43), a first insulating layer (5) over the working electrode, and a second insulating layer (34) over the counter electrode – Figures 1, 3, and 5);

(e) a spacer (43) between the first and second substrates (Figure 5) defining:

(i) a first aperture (50) along the proximal end of the sensor (Figure 5), and

(ii) a sample chamber (49) extending from the first aperture to a second aperture (51) (Drawing 2), the sample chamber comprising a measurement zone having a small volume of no more than 3 microliters (col. 12:35-39), and the sample chamber defining a recess having at least a portion of the working electrode and redox mediator situated in the recess (Figure 5 and col. 12:18-26).

Diebold does not mention having a portion of the counter electrode located 25-1000 micrometers from a portion of the at least one working electrode. Diebold, though, discloses using a MYLAR™ film as a spacer (col. 7:14-18 and col. 7:55-57), but does not disclose the thickness. Diebold also discloses using MYLAR™ film of approximately 10 mil (254 microns) thickness as an electrode support (col. 5: 62-67), which if not the same MYLAR™ film as used for the spacer is certainly an obvious variant. As shown by Straus, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. See col. 4:53-56. The spacing between the working electrode and counter electrode also has a contribution from a second insulating layer (5) over the working electrode and a second insulating layer (34) over the counter electrode. Diebold that these second insulating layers are a solder resists, such as ENPLATE®DSR-3242 (a negative resist). See col. 4:35-48. Product literature from Enthone discloses that ENPLATE®DSR-3242 could be made less than 1.1 mils thick (27.94 microns), for example 0.5 mils (12.7 microns). See Enthone. Also, it was known at the time of the invention to make a negative type photosensitive epoxy-solder resist (ENPLATE®DSR-3242 is such a resist) only 5 microns thick in a printed circuit board, which is clearly related art to Diebold. See in Kanezawa col. 8:9-16. Thus, barring

evidence to the contrary, such as unexpected results Applicants' claimed distance between the working electrode and the counter or counter/reference electrode of from about 25 microns to 1000 microns is just a matter of scaling the spacer of Diebold, such as by using the 12.2 micron thick Dupont Mylar film disclosed by Straus and thin second insulating layers as disclosed by Enthone and Kanezawa. A smaller spacer will create a smaller electrochemical cell effective volume, which is consistent with the purpose of the sensor of Diebold: "A method for fabricating high-resolution, biocompatible electrodes is disclosed, allowing production of an electrochemical sensor which is capable of precise analyte concentration determination on a <u>very small sample size</u>. [emphasis added]." See the abstract.

Diebold also does not mention configuring the measurement zone to have a volume of not more than 1 microliter. However, this is just a matter of scaling the spacer of Diebold. Hodges I discloses a sensor strip for determining the concentration of an analyte in a sample (the abstract) comprising:

(a) a first substrate (7) having a proximal end and an opposite distal end (Figure 9), the distal end, the first substrate defining a first edge (left side edge in Figure 9) and a second edge (right side edge in Figure 9) of the sensor extending from a proximal end to the distal end of the first substrate (Figure 9);

(b) a second substrate (1) positioned over the first substrate (Figure 9);

(c) at least one working electrode (6) on the first substrate (Figure 9); and

(d) at least one counter electrode (3) on the second substrate (Figure 9), with a portion of the counter electrode located 25-1000 micrometers from a portion of the at

least one working electrode (the working electrode and the counter electrode are separated by a spacer (4) that is 100 microns thick (col. 04:56-57 and col. 10:14-54);

(e) a spacer (4) between the first and second substrates (Figure 9) defining:

(i) a first aperture (left notch in Figure 9), and

(ii) a sample chamber (8) with a second aperture (right notch in Figure 9), the sample chamber comprising a measurement zone having a volume of no more than 1 microlitre (The sample chamber is 100 microns thick and has a 3.4 mm diameter. Some simple calculations reveal that the sample chamber has a cross-sectional area = 9.1 mm^2 and volume = 0.91 mm^3 = 0.91 microlitre), and the sample chamber defining a recess having at least a portion of the working electrode and redox mediator situated in the recess (col. 05:08-10).

Hodges II discloses a sensor strip comprising a cell made from opposing substrates with a working electrode on one substrate and a counter electrode on the other substrate; the electrodes being spaced apart by less than 500 microns, preferably 20-400 microns, and more preferably 20-200 microns; the effective cell volume, which includes the measurement zone, being 1.5 microlitres or less; and the cell containing redox mediator. See page 15, lines 17-23 and page 16, lines 08-12. An effective cell volume of 1.5 microlitres presumably corresponds to a spacing between the electrodes of 500 microns or at least 200 microns. So, a spacing between the electrodes of 20 microns, the lowest stated limit, should bring the effective cell volume significantly below 1 microlitre. Diebold is directed to a small volume sensor and discloses a cell volume of 3 microns. See the abstract and col. 12:35-42. The spacer, by its thickness and the

width of the capillary channel, defines the cell volume in Diebold. See Figure 5. It may be made of a plastic film, such as MYLAR™ film. See Figure 5 and col. 7:14-18 and col. 7:55-57. As noted above, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. Diebold also discloses using a laser to from a cutout that defines the capillary channel. See col. 7:14-21. Thus, barring evidence to the contrary, such as unexpected results, in light of Hodges I and Hodges II, which each disclose an electrochemical test strip with a measurement zone of no more than 1 microliter, having an effective cell volume of less than 1 microliter, or 0.5 microliter, or 0.2 microliter is just a matter of scaling the cell volume in Diebold by using a thin enough spacer, such as using the 12.2 micron thick Dupont Mylar film disclosed by Straus, and/or creating a narrow enough capillary channel by using thin enough laser beam. As taught by in the prior art "... sample size is greater than desirable. It would be generally preferable to be able to make measurements on samples of reduced volume since this in turn enables use of less invasive methods to obtain samples." See col. 02:35-40. This goal is consistent with a major purpose of the Diebold sensor: "A significant advantage to the present invention is the low volume required for the measurement, thus allowing for a very low pain lancet device which produces low sample volumes." See col. 12:39-42.

Addressing claim 2, the sample chamber in Diebold is substantially rectangular. However, barring some showing of criticality, the shape of the sample chamber is a design choice, especially since as shown by Figure 9 of Hodges I a circular sample chamber was known at the time of the invention.

Addressing claim 3, Diebold discloses making the working electrode from a noble metal or carbon. See col. 03:50-58.

Addressing claim 4, Diebold discloses making the counter electrode from an electrically conducting material, such as, silver/silver chloride. See col. 07:08-14. Hodges I discloses making the counter electrode from palladium. See col. 04:63-65. Hodges II disclose making the counter electrode from platinum. See page 16, lines 08-14. So, the choice of conducting material from which to make the counter electrode (and working electrode) from known conducting materials for such purpose will, barring evidence to contrary, such as unexpected results, depend on the desired measurement accuracy, the stability of the materials when contacted the sample, and the cost of the material. Carbon, for example, is cheaper than gold, but not as good a conductor.

Addressing claim 5, as discussed in the rejection of claim 1, Diebold as modified by Straus discloses a spacer only 12.2 microns thick.

Addressing claim 8, recall that Diebold as modified by Straus, Enthone, and Kanezawa spacer that is only 12.2 microns thick and a first insulating layer and a second insulating layer that is each only 12.7 microns thick. Barring a contrary showing, such as unexpected result, the thickness of the spacer plus that of the first and second insulating layers, which determines the spacing between the electrodes and can be just 37.6 microns, will be determined by the largest expected sample volume.

Addressing claims 11 and 12, for the additional limitation of this claim see in Diebold col. 12:24-32.

Addressing claim 13, for the additional limitation of this claim see in Diebold col. 10:14-54.

Addressing claim 15, for the additional limitation of this claim see in Diebold col. 10:35-41.

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus"), Kanezawa et al. (US 5,095,407) ("Kanezawa"), "Enthone – Imaging Technologies Update" June 2001/Number 3) ("Enthone"), Hodges et al. (US 5,942,102) ("Hodges I") and Hodges et al. (WO 97/00441) as applied to claims 1-5, 8-13, 15 and further in view of Maley et al. (US 5,601,694) ("Maley").

Diebold does not mention the working area of the working electrode.

Maley discloses an electrochemical sensor strip in which the working area of the working electrode is determined by the size of an opening in a dielectric layer over a conductive strip, which is how working area for the working electrode in Diebold is determined. See in Maley the abstract; Figure 9B; and col. 15 42-44; and col. 12:46-55. In Diebold see col. 05:03-10 and Figure 5. The working area of the working electrode in Maley is 0.00038 $inch^2$ (= 0.00025 cm^2). See col. 23:40-55. Thus, in light of Maley, since the sensor strip of Diebold is intended for use with a small amount of sample, to have the working area of the working electrode less than about 0.01 cm^2 is just a matter of scaling the sensor strip down for a smaller sample volumes.

11. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO English language machine translation of Ryohei et al. (JP 09-166571 A) ("Ryohei II") in view of Hodges et al. (US 5,942,102) ("Hodges I"), Hodges et al. (WO 97/00441) ("Hodges II"), and Kurnik et al. (US 5,989,409) ("Kurnik").

Addressing clams 16 and 19-21, Ryohei II discloses a sensor strip for determining the concentration of an analyte in a sample (the abstract) comprising:

(a) a first substrate (1a) having a proximal end and an opposite distal end (Drawing 2), the distal end being configured and arranged for insertion into a sensor reader (note connection terminal 232 and see [0013] in Detailed Description), the first substrate defining a first edge (left side edge in Drawing 1a) and a second edge (right side edge in Drawing 1a) of the sensor extending from a proximal end to the distal end of the first substrate (Drawing 1a);

(b) a second substrate (1b) positioned over the first substrate (Drawing 1b);

(c) at least one working electrode (221) on the first substrate (Drawing 2); and

(d) at least one counter electrode (222a, 222b) on one side of the first substrate (Drawing 2), with a portion of the counter electrode located from a portion of the at least one working electrode;

(e) a spacer layer (4) between the first and second substrate (Drawings 1(c) and (e)):

(i) a first aperture (61) along the proximal end of the sensor (Drawing 1(b)); and

(ii) a sample chamber (6) extending from the first aperture to a second aperture, the sample chamber comprising a measurement zone, and the sample camber defining a recess having at least a portion of the working electrode and a redox mediator situated in the recess (Drawing 1(b) and [0026] in the Detailed Description).

Ryohei II does not mention (a) the spacing between the electrodes, and (b) the size of the measurement zone. As for the spacing between the electrodes, as shown by Kurnik it was known at the time of the invention to have electrodes in an electrochemical sensor strip separated by a gap of from 50 microns to 1,000 microns. See the abstract and col. 07:25-45. Thus, barring a contrary showing, such as unexpected results, having a portion of the working electrodes located 25-1000 micrometers from a portion of the counter electrode is just a matter of scaling the sensor strip for the expected volume of sample, especially since a major aspect of the invention of Ryohei II is an improved method of efficiently and precisely manufacturing electrodes so that that sensor can easily measure a small amount of sample. See Effect of the Invention.

As for having the measurement zone having a volume of no more than 1 microliter, as noted above the sensor strip of Ryohei II is intended for use with a small sample.

Hodges I discloses a sensor strip for determining the concentration of an analyte in a sample (the abstract) comprising:

(a) a first substrate (7) having a proximal end and an opposite distal end

(Figure 9), the distal end, the first substrate defining a first edge (left side edge in Figure 9) and a second edge (right side edge in Figure 9) of the sensor extending from a proximal end to the distal end of the first substrate (Figure 9);

(b) a second substrate (1) positioned over the first substrate (Figure 9);

(c) at least one working electrode (6) on the first substrate (Figure 9); and

(d) at least one counter electrode (3) on the second substrate (Figure 9), with a portion of the counter electrode located 25-1000 micrometers from a portion of the at least one working electrode (the working electrode and the counter electrode are separated by a spacer (4) that is 100 microns thick (col. 04:56-57);

(e) a spacer (4) between the first and second substrates (Figure 9) defining:

(i) a first aperture (left notch in Figure 9), and

(ii) a sample chamber (8) with a second aperture (right notch in Figure 9), the sample chamber comprising a measurement zone having a volume of no more than 1 microlitre (The sample chamber is 100 microns thick and has a 3.4 mm diameter. Some simple calculations reveal that the sample chamber has a cross-sectional area = 9.1 mm^2 and volume = 0.91 mm^3 = 0.91 microlitre), and the sample chamber defining a recess having at least a portion of the working electrode and redox mediator situated in the recess (col. 05:08-10).

Hodges II discloses a sensor strip comprising a cell made from opposing substrates with a working electrode on one substrate and a counter electrode on the other substrate; the electrodes being spaced apart by less than 500 microns, preferably 20-400 microns, and more preferably 20-200 microns; the effective cell volume, which

includes the measurement zone, being 1.5 microlitres or less; and the cell containing redox mediator. See page 15, lines 17-23 and page 16, lines 08-12. An effective cell volume of 1.5 microlitres presumably corresponds to a spacing between the electrodes of 500 microns or at least 200 microns. So, a spacing between the electrodes of 20 microns, the lowest stated limit, should bring the effective cell volume significantly below 1 microlitre.

Thus, barring evidence to the contrary, such as unexpected results, in light of Hodges I and Hodges II having the measurement zone volume in the sensor strip of Ryohei II be no more than 1 microliter, or 0.5 microliter, or 0.2 microliter is just a matter of scaling down the dimensions of the sensor strip, in particular, this can be achieved by just using a thinner spacer (Ryohei II discloses a spacer of only 50-300 microns thick – [0022] in the Detailed Description), so that the sensor strip is optimally configured for smaller sample volumes.

Moreover, as taught by Hodges I in the prior art "... sample size is greater than desirable. It would be generally preferable to be able to make measurements on samples of reduced volume since this in turn enables use of less invasive methods to obtain samples." See col. 02:35-40.

Addressing claim 17, the sample chamber in Ryohei II is substantially rectangular. However, barring some showing of criticality, the shape of the sample chamber is a design choice, especially since as shown by Figure 9 of Hodges I a circular sample chamber was known at the time of the invention.

Addressing claim 18, as stated in the rejection of claim 1 the spacer (4) in Ryohei II is 50-300 micrometers thick ([0022] in Detailed Description). So having the spacer thickness no more than 0.2 mm (200 micrometers) is just a matter of scaling down the sensor for a range of smaller sample volumes than would be used if the spacer were more than 200 microns.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-10 and 12- 21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Heller et al. (US 6,120,676). See the abstract; Figures 1, 2, 5, and 6; col. 05:50-55; col. 07:05-41; col. 19:20-21; col. 17:24-32; col. 10:38-42; and col. 19:59 – col. 20:06.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Priority

14. This application repeats a substantial portion of prior Application No. 09/594,285, filed June 13, 2000, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Although prior Application No. 09/594,285 discloses two embodiments in which

the sample chamber recess is circular (Figures 1 and 2) in neither of these embodiments is there a second aperture associated with the sample chamber. Thus, at least with regard to claims 2 and 17, the instant application is more appropriately a continuation-in-part instead of a continuation of Application No. 09/594,285.

Information Disclosure Statement ("IDS")

15. Applicant is requested to provides copies of the following references

a) US 5,781,455, Hyodo, which is cited on page 9 of the IDS of December 15, 2003. Although a U.S. Patent, it appears to have been pulled from issue and is not in the Examiner's files for the parent applications of the instant application;

b) EP 537761 A2, which is cited on page 11 of the IDS of December 15, 2003;

c) WO 91/09139, which is cited on page 12 of the IDS of December 15, 2003;

d) WO 98/35225, WO 98/43073, and WO 98/58250 which are cited on page 13 of the IDS of December 15, 2003; and

e) the article by Vidal et al. (*Sensors and Actuators* B 21, pp. 135-141 (1994)), which is cited on page 13 of the IDS of December 15, 2003.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 30, 2007